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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,455

08/24/2006

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Q96638

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23373 7590 07/08/2009  
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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

07/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/590,455	TANAAMI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/08</u>   | 6) <input type="checkbox"/> Other: _____                          |

## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 13 April 2009 in which claims 1-5 were amended and claims 12-16 were added. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 12 January 2009, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 1-16 are under prosecution.

### ***Information Disclosure Statement***

2. Applicant requests that the Examiner consider the foreign language documents listed on the 1449 filed 27 May 2008. It is noted that the US Patents listed on the 1449 were not initialed previously. The corrected 1449 is enclosed with this Office Action. The foreign language documents listed on the 1449 cite corresponding US documents, which are also listed on the 1449. The US documents have been reviewed and considered, but the foreign language documents have not been reviewed or considered.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Holzel et al (Biosensor and Bioelectronics, 2003 18: 555-564).

Regarding Claims 1 and 2, Holzel et al disclose a microarray substrate comprising a pair of conduction paths (i.e. 2 neighboring electrodes) connected to alternating current source wherein the electrodes are arranged in proximity to each other such that an electric field is locally stronger and wherein probes are immobilized on the electrodes (Fig. 1-2, Abstract, § 2.2, § 2.3, § 3.1). Holzel further teaches probes immobilized “close to” the conduction paths (Fig. 1-2). The electrode-immobilized probes are encompassed by the immobilization “on the conduction paths” because the electrodes are conductive and. Additionally, the electrode-immobilized probes are encompassed by the immobilization “close to its proximity part” because the probes are immobilized in the region where the neighboring electrodes are in proximity to one another (Fig. 2).

Regarding Claim 3, Holzel et al disclose the microarray having two or more proximity parts i.e. multiple gaps formed by interdigitated electrodes (Fig. 2 & 4).

Regarding Claim 4, Holzel et al disclose the microarray wherein the substrate is glass (§ 2.1.1) and the conductive paths are formed by printing (§ 2.2.1). While the

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reference teaches formation of the electrodes as claimed, the method of making the electrodes does not define the microarray over other methods of making the same microarray.

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Regarding Claim 7, Holzel et al disclose the device of Claim 1 further comprising a power source for supply AC voltage (page 560, left column, first full paragraph).

Regarding Claim 8, Holzel et al disclose the device of Claim 7 further comprising a glass/transparent cover opposite the substrate (§ 2.2.4 and Fig. 3).

Regarding Claim 9, Holzel et al disclose the device wherein the electrodes are formed on glass (i.e. transparent material) and further teaches fluorescent detection (§ 2.1.1 and § 2.2.4).

Regarding Claim 10, Holzel et al disclose a method of performing hybridization comprising applying AC voltage to the conductive paths in the device of Claim 7 whereby the biopolymer is concentrated via dielectrophoresis (§ 3.1).

Regarding Claim 11, Holzel et al disclose the method wherein the biopolymer is detected by fluorescent signal following hybridization (Fig. 6).

### **Response to Arguments**

5. Applicant asserts that Holzel does not anticipate the invention as claimed because the reference is not related to hybridization of a sample. The assertion is noted but is not persuasive because Holzel clearly illustrates hybridization (Fig. 1) and because the recitation of intended use (i.e. "for hybridization") does not further define the structure of the claimed invention over that of Holzel. The courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Applicant asserts that Holzel fails to teach a pair of two conduction paths as required by Claim 2 wherein the probes are immobilized close to the opposed substrates proximity parts. The argument has been considered but is not found persuasive. As noted above, the claims are broadly drawn to "close to" proximity part. It is maintained that the reference clearly illustrates the invention as broadly claimed (Fig. 1-2).

Applicant further argues that Holzel merely teaches a glass substrate but does not teach fluorescence labeling can be observed from the back face of the glass as required by Claim 9. The argument has been considered but is not found persuasive because, as cited above, the reference specifically teaches optical detection of fluorescence labels and transparent substrates (§ 2.1.1 and § 2.2.4).

Applicant notes that Claim 4 requires that the conduction paths are formed by etching. Applicant asserts that the claimed etching "would result in a substantive

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difference in structure than what is disclosed by Holzel". The assertion is noted, however because the assertion is not supported by any evidence of the asserted difference in structure, the assertion is deemed arguments of counsel. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. (see MPEP § 716.01(c). *Applicant is informed that this is not an invitation to submit a Declaration because a Declaration submitted after Final Office Action would not be considered timely (see MPEP § 716.01).*

6. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Zenhausern et al (U.S. Patent Application Publication No. 2004/0011650, published 22 January 2004).

Regarding Claims 1 and 2, Zenhausern et al disclose a microarray substrate comprising a pair of conduction paths (i.e. interdigitated electrodes) connected to direct current and alternating current source (¶ 272) wherein the electrodes are arranged in proximity to each other such that an electric field is locally stronger (¶ 272) and wherein

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probes are immobilized on the electrodes (i.e. capture probes, ¶ 14, ¶ 24, ¶ 272 and Fig. 3-4). The electrode-immobilized probes are encompassed by the immobilization “on the conduction paths” because the electrodes are conductive and. Additionally, the electrode-immobilized probes are encompassed by the immobilization “close to its proximity part” because the probe are immobilized in the region where the neighboring electrodes are in proximity to one another (Fig. 3-4).

Regarding Claim 3, Zenhausern et al disclose the microarray having two or more proximity parts i.e. multiple gaps formed by interdigitated electrodes and multiple sets of interdigitated electrodes (Fig. 3 & 4).

Regarding Claim 4, Zenhausern et al disclose the microarray wherein the substrate is glass, ceramic or plastic (¶ 44) and the conductive paths are formed by printing (¶ 55). While the reference teaches formation of the electrodes formed by printing, the method of making (e.g. etching) the electrodes does not define the microarray over other methods of making the same microarray (see MPEP 2113).

Regarding Claim 5, Zenhausern et al disclose the device wherein the paths are insulated i.e. monolayer thus serves as a physical barrier to block solvent accessibility to the detection electrode(¶ 221).

Regarding Claim 6, Zenhausern et al disclose the device further comprising an electrode, separate from the immobilization electrode, for detecting hybridization (¶ 247-250).

Regarding Claim 7, Zenhausern et al disclose the device of Claim 1 further comprising a power source for supplying DC and AC voltage (¶ 57-58, ¶ 272).



Regarding Claim 10, Zenhausern et al disclose a method of performing hybridization comprising applying AC voltage to the conductive paths in the device of Claim 7 whereby the biopolymer is concentrated via dielectrophoresis (§§ 205-207).

Regarding Claim 11, Zenhausern et al disclose the method wherein the biopolymer is detected by fluorescent signal following hybridization (§§ 212-213).

Regarding Claim 12, Zenhausern discloses the device of Claim 1 having a cylindrical shape on the substrate (i.e. cylindrical chamber, § 46).

Regarding Claim 13, Zenhausern discloses the microarray wherein the substrate is glass, ceramic or plastic (§ 44) and the conductive paths are formed by printing (§ 55).

Regarding Claims 14-15, Zenhausern discloses the device of Claim 1 further comprising a power source for supplying DC and AC voltage (§§ 57-58, § 272) and selective application of DC and AC voltage (§ 272). While the reference teaches selective application of DC and AC, the method of using the device as claimed does not structurally define the device.

### **Response to Arguments**

7. Applicant asserts that Zenhausern does not teach immobilization of probes for hybridization as claimed. The assertion is noted, however Zenhausern specifically teaches immobilized probes (e.g. § 24, 33, 108) and hybridization (e.g. § 33).

Applicant further argues that Zenhausern does not teach that a current is applied to wires insulated with a nonconductive film. The argument is not found persuasive because as Applicant notes, the reference teaches electrode insulation which is clearly encompassed by the lead wires as claimed because the instant specification does not provide a limiting definition for "lead wire". Furthermore, Zenhausern specifically teaches insulating materials (e.g. ¶ 48, 245).

Applicant further argues that Zenhausern does not teach probes immobilized "close to" proximity parts, as required by Claim 2 or substrate formed by etching as required by Claim 4. The arguments are not found persuasive for reasons similar to those discussed above regarding Holzel. It is maintained that the prior art teaches the invention as broadly claimed.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zenhausern et al (U.S. Patent Application Publication No. 2004/0011650, published 22 January 2004) in view of Holzel et al (Biosensor and Bioelectronics, 2003 18: 555-564).

Regarding Claims 8-9, Zenhausern et al disclose a microarray substrate comprising a pair of conduction paths (i.e. interdigitated electrodes) connected to direct current and alternating current source (§ 272) wherein the electrodes are arranged in proximity to each other such that an electric field is locally stronger (§ 272) and wherein probes are immobilized on the electrodes (i.e. capture probes, ¶ 14, ¶ 24, ¶ 272 and Fig. 3-4).

Zenhausern et al further teach the substrate is glass (§ 44) and wherein the biopolymer is detected by fluorescent signal following hybridization (§ 212-213) but the reference is silent regarding a transparent cover whereby fluorescence can be viewed for back or top. However, Holzel teach a similar device comprising a glass/transparent cover opposite the substrate (§ 2.2.4 and Fig. 3) wherein the electrodes are formed on glass (i.e. transparent material) and further teaches fluorescent detection (§ 2.1.1 and § 2.2.4). Holzel et al further teach the arrangement provides ease of handling and electrical connection (page 560, lines 7-10).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the glass cover of Holzel to the device of Zenhausern. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the benefit of providing ease of handling and electrical connection as taught by Holzel (page 560, lines 7-10).

### **Response to Arguments**

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10. Applicant asserts that Zenhausern fails to cure the deficiencies of Holzel. The argument is not found persuasive because as stated above, the references are not found deficient.

11. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Zenhausern et al (U.S. Patent Application Publication No. 2004/0011650, published 22 January 2004).

Regarding Claim 16, Zenhausern explicitly teaches the channels (§ 47) and electrodes (§ 55) can be of “any shape” but does not specifically teaches circle, spiral or annular shapes. The courts have stated that absent evidence to the contrary, a particular configuration of a known device is a matter of choice which would have been obvious to one skilled in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the electrodes of Zenhausern in circular or spiral shape to conform to available equipment. The ordinary artisan would have been motivated to do so with a reasonable expectation of success based on the reference's teaching that any shape would be useful.

### ***Conclusion***

12. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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